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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,200	07/18/2003	Thomas P. Osypka	(49363) 58952	2841

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/623,200	<b>Applicant(s)</b> OSYPKA, THOMAS P.	
	<b>Examiner</b> Kristen Mullen	<b>Art Unit</b> 3766	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/17/04 (address change).
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/12/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/9/04</u> 3 | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Specification*

1. The abstract of the disclosure is objected to because it includes phrases which can be implied such as "... is disclosed ...". Correction is required. See MPEP § 608.01(b).
2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The *disclosure* concerns," "The *disclosure* defined by this invention," "The *disclosure* describes," etc.

3. The disclosure is objected to because of the following informalities: typographical error on page 3, line 13 and typographical error on page 11, line 10 where "26a" should be changed to --126a--.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 13-14 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 13-14 each recite the limitation "the at least one lumen" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, 5, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Xavier (5,458,631).

Regarding claim 1, Xavier shows an elongated lead body (12) having opposed proximal and distal end portions and having at least one lumen (17) extending therethrough; an electrode assembly (14) operatively associated with the distal end portion of the lead body; a connector assembly operatively associated with the proximal end portion of the lead body, the connector assembly having an engagement stem (26) depending therefrom and a ported connector fitting (threaded syringe fitting) having a body with an engagement bore and having at least one passageway extending therethrough, in communication with the engagement bore (Col. 6, line 10-44; Figs. 1-2).

With respect to claims 3 and 11, Xavier shows the engagement stem (26) of the connector assembly and the engagement bore of the ported connector fitting are threaded (Col. 6, line 10-44; Figs. 1-2).

Regarding claims 5 and 13, Xavier shows at least one lumen (17) formed in the lead body has an outlet port (30) at the distal end of the lead body (Fig. 2).

9. Claims 1-2 and 4-10 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Clemens et al. (2002/0077684).

Regarding claim 1, Clemens shows an elongated lead body having opposed proximal and distal end portions and having at least one lumen extending therethrough; an electrode assembly (16) operatively associated with the distal end portion of the lead body; a connector assembly (50) operatively associated with the proximal end portion of the lead body, the connector assembly having an engagement stem (54) depending therefrom and a ported connector fitting (58) having a body with an engagement bore and having at least one passageway (104) extending therethrough, in communication with the engagement bore (Fig. 1).

With respect to claim 2, Clemens shows the ported connector fitting (58) has a bifurcated body that includes a first portion having a first passageway extending therethrough (60), in communication with the engagement bore, and a second portion having a second passageway (61) extending therethrough, in communication with the engagement bore (Fig. 1).

Regarding claim 4, Clemens shows at least one passageway formed in the ported connector (58) fitting has a funnel-shaped inlet region (where stylet assembly 62 is introduced).

With respect to claims 5-6, Clemens shows at least one lumen (114) formed in the lead body has an outlet port at the distal end of the lead body and at least one lumen (104) formed in the lead body has an outlet port (102) at a location spaced from the distal end of the lead body (Fig. 2).

Art Unit: 3766

Regarding claim 7, Clemens shows the electrode assembly is bipolar and includes a distal tip electrode (16) and a proximal ring electrode (20) (Fig. 2).

With respect to claim 8, Clemens shows a helical conductor coil (138, 140) extending through the lead body for connecting the electrode assembly with the connector assembly (para. [0047]).

Regarding claim 9, Clemens discloses a helical fixation screw operatively associated with the distal end of the lead body for actively securing the lead to cardiac tissue (Col. 7, line 46-51).

With respect to claim 10, Clemens shows a plurality of flexible tines (162) provided at the distal end of the lead body.

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemens et al. (2002/0077684) in view of Westlund et al. (2002/0077683)

Regarding claim 11, Clemens shows an elongated lead body having opposed proximal and distal end portions and having a lumen extending therethrough; an electrode assembly (16) operatively associated with the distal end portion of the lead body; a connector assembly (50) operatively associated with the proximal end portion of the lead body, the connector assembly

Art Unit: 3766

having an engagement stem (54) depending therefrom and a ported connector fitting (58) having a body with an engagement bore and having at least one passageway (104) extending therethrough, in communication with the engagement bore (Fig. 1).

Although Clemens shows a connector assembly with an engagement stem (54) and ported connector with an engagement bore, and it isn't clear how they are coupled, Clemens fails to show the engagement stem and engagement bore are threaded. Attention is directed to Westlund who shows a similar connector assembly (860) and ported connector (820) that utilizes threads for coupling the connector assembly and ported connector (Fig. 9). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ threads on the engagement stem and engagement bore for the coupling of the engagement stem and engagement bore of Clemens wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Clemens device. MPEP 2144.06, *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

Regarding claim 12, Clemens shows at least one passageway formed in the ported connector (58) fitting has a funnel-shaped inlet region (where stylet assembly 62 is introduced).

With respect to claims 13-14, Clemens shows at least one lumen (114) formed in the lead body has an outlet port at the distal end of the lead body and at least one lumen (104) formed in the lead body has an outlet port (102) at a location spaced from the distal end of the lead body (Fig. 2).

Regarding claim 15, Clemens shows the electrode assembly is bipolar and includes a distal tip electrode (16) and a proximal ring electrode (20) (Fig. 2).



With respect to claim 16, Clemens shows a helical conductor coil (138, 140) extending through the lead body for connecting the electrode assembly with the connector assembly (para. [0047]).

Regarding claim 17, Clemens discloses a helical fixation screw operatively associated with the distal end of the lead body for actively securing the lead to cardiac tissue (Col. 7, line 46-51).

With respect to claim 18, Clemens shows a plurality of flexible tines (162) provided at the distal end of the lead body.

12. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemens et al. (2002/0077684) in view of Westlund et al. (2002/0077683) and further in view of Alt (5,868,245).

Regarding claim 19, Clemens shows an implantable lead having an elongated lead body with a lumen extending therethrough; and including a connector assembly (50) operatively associated with a proximal end portion of the lead body, the connector assembly having an engagement stem (54) depending therefrom; at least one ported connector fitting (58) having a body with an engagement bore and having a passageway (104) extending therethrough (Fig. 1).

Although Clemens shows a connector assembly with an engagement stem (54) and ported connector with an engagement bore, and it isn't clear how they are coupled, Clemens fails to show the engagement stem and engagement bore are threaded. Attention is directed to Westlund who shows a similar connector assembly (860) and ported connector (820) that utilizes threads for coupling the connector assembly and ported connector (Fig. 9). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ threads on the



Art Unit: 3766

engagement stem and engagement bore for the coupling of the engagement stem and engagement bore of Clemens wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Clemens device. MPEP 2144.06, *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

Although Clemens and Westlund fail to show an enclosure, attention is directed to Alt who teaches it is well known to utilize enclosures in order to maintain implantable devices and tools in sterile condition between manufacture and use (Col. 1, lines 19-25). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include an enclosure for the kit of Clemens as modified by Westlund since Alt teaches that it is well known to utilize enclosures or packaging in order to maintain implantable devices and tools in sterile condition between manufacture and use.

Regarding claim 20, Clemens shows a lumen (114) extending through the lead body and a multi-ported connector fitting having a bifurcated body having a first passageway (60) extending therethrough and a second passageway (61) extending therethrough (Figs. 1-2).

With respect to claim 21, Clemens shows an elongated guidewire (115) (Fig. 2).

Regarding claim 22, Clemens discloses a helical fixation screw operatively associated with the distal end thereof and the kit includes a stylet (62) of the lead body for actively securing the lead to cardiac tissue (Col. 7, line 46-51). Clemens further discloses that the stylet can be screwdriver tipped stylet via incorporation by reference of U.S. Pat No. 4,350,169 (paras [0049-0050]).

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

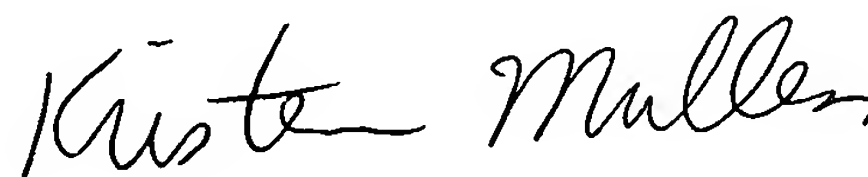
*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Mullen  
Patent Examiner  
Art Unit 3766



kdm